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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,915	07/22/2003	D. Russell Pflueger	QMI-3077	7109
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EXAMINER				
PATEL, NIHIR B				
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07/23/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,915

Applicant(s)

PFLUEGER ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-55, 66-68, 70-78, 80-83 and 85-107 is/are pending in the application.
- 4a) Of the above claim(s) 95 and 96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-55, 66-68, 70-78, 80-94 and 97-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

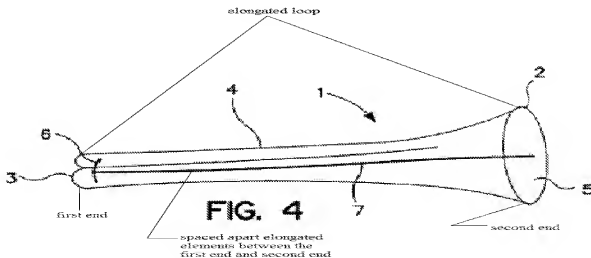
Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/11/2009.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on April 27th, 2009 have been fully considered but they are not persuasive. The applicant argues that Zammit reference does not teach or suggest an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions. The examiner disagrees with the applicant's argument. Figure 4 of the Zammit shows an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions. Col. 4 lines 11-14 of the clearly recites that "The device can be held in this collapsed state by one or more retaining mechanisms 6 such as a retaining fiber, tie or clasp. These retaining fibers can be connected between points around the circumference of the device or they can, for example, be tied around the entire circumference of the device" implying that there are two spaced apart elongated elements extending between the first and second end portions.



The applicant further argues that Zammit reference fails to disclose, teach or suggest an appliance deployable in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall of the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region. The examiner disagrees with the applicant's argument. First the examiner would like to point out that the recitation "an appliance deployable in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall of the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Zammit's invention is capable of being deployed in a C-shaped deployed configuration in which at least one of the elongated elements extends generally laterally across the posterior wall of the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region as figure 3 shows a substantially C shaped configuration and inherently the retaining mechanism can be adjusted to form a C-shaped configuration. The Zammit reference also clearly recites "In an embodiment shown in fig. 6, a patient inserts the collapsed nasal-oropharyngeal tube via the nostril and through the nasal passage until the device is properly positioned" the phrase "oropharyngeal tube' inherently implies that the device bears against and provide an opening force against the lateral walls of the propharyngeal region as fig. 6 of the Zammit reference shows.

The applicant further argues that the flared end of Zammit reference are incapable of bearing against and providing an opening force against the lateral walls of the oropharyngeal region. Again the examiner disagrees; figure 6 of the Zammit reference shows the flared end capable of bearing against and providing an opening force against the lateral walls of the oropharyngeal region.

The applicant further argues that the Zammit reference fails to disclose, teach or suggest an appliance that includes two elongated curved elements coupled together at respective first and second ends. More particularly, the Zammit reference does not disclose, teach or suggest that each of the curved elements has a substantially circular dimension between a first and second end extending through more than 90 degrees of a circle, the two elements being coupled together at respective first and second ends, and being spaced apart from each other between the first and second ends to define an open interior space therebetween. The examiner disagrees with the applicant's argument. Figures 1-4 of the Zammit reference teach an appliance that includes two elongated curved elements coupled together at respective first and second ends and that each of the curved elements has a substantially circular dimension between a first and second end extending through more than 90 degrees of a circle, the two elements being coupled together at respective first and second ends, and being spaced apart from each other between the first and second ends to define an open interior space therebetween.

The applicant argues that Zammit's device is not sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall. The examiner disagrees with the applicant's argument. Figure 6 of the

Zammit reference shows that the device is sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall.

The applicant further argues that Zammit reference does not teach or suggest providing an appliance below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal. The examiner disagrees with the applicant's argument. The distal end of the soft palate where reference character 12 is pointing to is defined as below a soft palate.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **93, 94, 97 and 100** are rejected under 35 U.S.C. 102(b) as being anticipated by Zammit (US 6,328,753).
4. **As to claims 93 and 100**, Zammit teaches an apparatus that comprises an appliance comprising an elongated loop comprising first and second end portions and two spaced apart elongated elements extending between the first and second end portions (**see figures 1-4**), the appliance being sized for introduction into an oropharyngeal region of a human or animal (**see col. 2 lines 30-50**) and deployable in a C shaped configuration in which at least one of the

elongated elements extend generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region (see col. 2 lines 30-60).

5. As to claim 94, Zammit teaches an apparatus wherein the appliance defines an open interior space between the spaced apart elongated elements (see figures 1-4).
6. As to claim 97, Zammit teaches an apparatus wherein, in the substantially C shaped configuration, the first and second end portions define a gap therebetween (see figure 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 82, 83, & 85-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zammit (US 6,328,753) in view of Conrad et al. (US 6,250,307).

10. **As to claims 82 and 92**, Zammit substantially discloses an apparatus that comprises an appliance comprising two elongated curved elements **2 and 3** (see **figures 1, 2 and 4; see col. 4 line 1-15**) each of the curved elements having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle (see **figures 1, 2 and 4**), the two elements being coupled together at respective first and second ends (see **figures 1, 2 and 4**), and being spaced apart from each other between the first and second ends to define an open interior space therebetween (see **figures 1, 2 and 4**), the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and, when so placed, being effective in treating sleep apnea (see **col. 2 lines 30-50**); wherein the appliance includes only two elongated curved elements, each of the curved elements has a curved lengths extending from the first end to the second end, and the first end and the second end define a gap therebetween extending outwardly away from the first and second curved elements having a gap length which is reduced relative to the curved length of each of the curved elements (see **figures 1, 2 and 4**) but does not disclose two elongated curved elements made of a biocompatible metal. Conrad discloses an apparatus that states that materials like titanium and nitinol are materials that can be used to make strips that are placed in the human body (see **col. 5 lines 50-67 and col. 6 lines 1-10**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zammit's invention by providing two elongated curved elements made of a biocompatible metal as taught by Conrad in order to prevent the patient from being infected.

11. **As to claim 83**, Zammit substantially discloses an apparatus wherein the substantially circular dimension between the first and second ends extends through at least 180 degrees of a circle (see figures 1-3).
12. **As to claim 85**, Zammit substantially discloses an apparatus wherein each of the two elongated elements comprises a resilient wire (see col. 4 lines 1-27).
13. **As to claim 86**, Zammit substantially discloses an apparatus wherein the appliance comprises a C shaped structure (see figure 3).
14. **As to claim 87**, Zammit substantially discloses an apparatus wherein the two elongated elements are portions of the same structure (see figures 1-4).
15. **As to claim 88**, Zammit substantially discloses an apparatus wherein the appliance has a lateral dimension defined by the distance between the first and second ends and a maximum longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension (see figure 4).
16. **As to claim 89**, Zammit substantially discloses an apparatus wherein the appliance has a concave loop configuration when the appliance is so placed in the oropharyngeal region (see figures 1 and 2; col. 2 lines 30-50).
17. **As to claim 90**, Zammit substantially discloses an apparatus wherein the appliance is sized and structured to be palced below a soft palate of a human or animal (see col. 4 lines 25-50).
18. **As to claim 91**, Zammit substantially discloses an apparatus wherein the appliance is made of an elastic spring memory material (see col. 3 lines 55-65).

19. Claims **98, 99 and 101** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zammit (US 6,328,753) in view of Conrad et al. (US 6,250,307).

20. **As to claim 99 and 101**, Zammit substantially discloses the claimed invention; see rejection of claims 93 and 100, but does not disclose the appliance that comprises biocompatible metal. Conrad discloses an apparatus that states that materials like titanium and nitinol are materials that can be used to make strips that are placed in the human body (see col. 5 lines 50-67 and col. 6 lines 1-10). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zammit's invention by providing two elongated curved elements made of a biocompatible metal as taught by Conrad in order to prevent the patient from being infected.

21. **As to claim 98**, Zammit/Conrad substantially discloses the claimed invention; see rejection of claim 93 above, but does not disclose an appliance expands to a diameter greater than 32 mm in the deployed configuration. Therefore, it would have been obvious matter of design choice to modify Zammit/Conrad invention by providing an appliance expands to a diameter greater than 32 mm in the deployed configuration since the expansion of the device depends on the size and age of the patient.

22. Claims **52-55, 66-68, 70-78, 80, 81 and 102-107** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zammit (US 6,328,753) in view of Conrad et al. (US 6,250,307).

23. **As to claim 52-55, 66-68, 70-78, 80 and 81**, Zammit/Conrad substantially discloses a method steps of providing an appliance made of a biocompatible metal (see col. 5 lines 50-67 and col. 6 lines 1-10 of the Conrad reference) below a soft palate of a human or animal in or

radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal (**see col. 2 lines 30-50**), the appliance so provided having at least two laterally positioned elements substantially longitudinally spaced apart from each other to define an open interior space therebetween and providing an opening force against the lateral walls of the oropharyngeal region (**see figures 1-4**).

The method steps would have been obvious because they would have resulted from the use of the device of Zammit/Conrad.

24. **As to claims 102-107**, Zammit/Conrad substantially discloses a method steps of providing an appliance comprising a continuous loop comprising first and second end portions and two spaced apart elongated extending between the first and second end portions (**see figures 1-4**); introducing the appliance into an oropharyngeal region (**see col. 2 lines 30-50**); and releasing the appliance within the oropharyngeal region such that the elongated elements extends generally laterally across the posterior wall and the first and second end portions bear against and provide an opening force against the lateral walls of the oropharyngeal region (**see col. 30-67**).

The method steps would have been obvious because they would have resulted from the use of the device of Zammit/Conrad.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772